JUN 1 2 2014

Medtronic

Traditional 510(k) Summary

Submitter: Medtronic Vascular
37A Cherry Hill Drive
Danvers, MA 01923,
USA

Contact Person: Nisarg Shah
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Date Prepared: June 6, 2014

Trade Name: Cougar™ Guidewires
Zinger™ Guidewires
Thunder™ Guidewires
ProVia™ Guidewires
Intuition™ Guidewires

Common Name: PTCA Guidewire

Classification Name: Catheter guide wire
Class II per 21 CFR §870.1330, Product Code DQX.

Predicate Device: The following commercialized Medtronic PTCA Guidewires were used as predicate devices in the 510(k) submission:

1) K091582 (ProVia 3, 6, 9 and Intuition)
2) K100470 (ProVia 12)
3) K970466 (Thunder)
4) K983927 (Zinger)
5) K032899 (Cougar)

Device Description: Medtronic PTCA Guidewires are steerable guidewires that are used during the Percutaneous Coronary Intervention (PCI) to reach a lesion or vessel segment by serving as a guide for other diagnostic or interventional devices in the coronary and

peripheral vasculature. The guidewires may also be used to reach and cross a target lesion within the coronary and peripheral vasculature excluding the cerebral vasculature. Once the tip of the guidewires arrive at a target destination within the vasculature, it acts as a guide that larger catheter can rapidly follow for easier delivery to the treatment site in the coronary and peripheral vasculature.

Statement of Intended Use:

Medtronic ProVia™ and Intuition™ Guidewires:
Medtronic [ProVia™ and Intuition™] GTX guide wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. Medtronic guide wires are not intended for use in the cerebral vasculature. Medtronic steerable exchange wires are used to facilitate the substitution of one diagnostic or interventional device for another.

Thunder™ Guidewires:
Medtronic [Thunder™] PTCA guidewire is indicated to facilitate the placement of balloon dilatation catheters during PTCA and/or PTA.

Zinger™ Guidewires:
Medtronic [Zinger™] guide wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. [Zinger™] guide wires are not intended for use in the cerebral vasculature. Medtronic steerable exchange wires are used to facilitate the substitution of one diagnostic or interventional device for another.

Cougar™ Guidewires:
Medtronic Cougar™ wire is intended for placement of balloon dilatation catheters during PTCA and/or PTA.

Summary of Technological Characteristics:

Medtronic Guidewires consist of a corewire covered with spring coils and terminated in a variable tip design to impart varied characteristic to the distal section of the wire, such as tip stiffness. Medtronic guidewires are coated to impart sufficient lubricity to reach and cross target lesions. There are

marker bands on few Medtronic Guidewires to help in gauging guidewire position in the vasculature. The technological characteristics of the Medtronic PTCA Guidewires are identical to the predicate devices legally marketed by Medtronic.

Summary of Non-clinical Data:

The device performance/ bench tests and biocompatibility tests were conducted in accordance to the relevant FDA guidance to demonstrate substantial equivalence to the legally marketed predicate devices.

Performance/ Bench Testing: The following bench tests were performed to demonstrate the substantial equivalence to the predicate PTCA Guidewires:

i. Coating Integrity
ii. Particulate evaluation
iii. Outer Diameter Measurement.

Biocompatibility Testing: Pursuant to the ISO 10993-1: 2009- *Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process;* the biocompatibility testing for the modified PTCA Guidewires.

No new safety or effectiveness concerns were raised during the testing on the modified device. The performance testing along with biocompatibility testing demonstrated that the modified PTCA Guidewires is safe, effective and performs as well or better than the predicate device.

Summary of Clinical Data:

No clinical investigation has been performed on the modified device.

Conclusion from Data:

Medtronic Vascular has demonstrated that the modified PTCA Guidewires are substantially equivalent to the legally marketed predicate devices based on its intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 12, 2014

Medtronic Vascular Inc.
% Nisarg Shah, Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, MA 01923 US

Re: K140695

Trade/Device Name:	Cougar™ Guidewires, Zinger™ Guidewires, Thunder™ Guidewires, ProVia™ Guidewires, Intuition™ Guidewires
Regulation Number:	21 CFR 870.1330
Regulation Name:	Catheter Guidewire
Regulatory Class:	Class II
Product Code:	DQX
Dated:	April 3, 2014
Received:	April 4, 2014

Dear Mr. Shah,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K140695

Device Name: Medtronic PTCA Guidewires (Cougar™, Zinger™, Thunder™, ProVia™ and Intuition™).

Indications for Use:

Medtronic ProVia™ and Intuition™ Guidewires:
Medtronic [ProVia™ and Intuition™] GTX guide wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. Medtronic guide wires are not intended for use in the cerebral vasculature. Medtronic steerable exchange wires are used to facilitate the substitution of one diagnostic or interventional device for another.

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Cougar™ Guidewires:
Medtronic Cougar™ wire is intended for placement of balloon dilatation catheters during PTCA and/or PTA.

Prescription Use ☑ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

PAGE 1 OF __